Supreme Court, U.S.
FILED
MAR 5 1993
OFFICE OF THE CLERK

No. 92-1345

IN THE

Supreme Court of the United States

October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE
and DR. ROLAND MERTELSMANN,

Petitioners,

v.

SLOAN-KETTERING INSTITUTE FOR
CANCER RESEARCH,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

STEVEN B. ROSENFELD
1285 Avenue of the Americas
New York, New York 10019-6064
(212) 373-3000
Counsel of Record for Respondent

Of Counsel:

CATHERINE J. ROSS
KATHLEEN M. WALKER

PAUL, WEISS, RIFKIND, WHARTON & GARRISON

COUNTERSTATEMENT OF THE QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit and the United States District Court for the Southern District of New York properly held that 35 U.S.C. § 202(c)(7)(B) was not intended to circumvent free market forces either by establishing minimum royalty sharing ratios for inventors or by empowering courts or juries to determine such inventors' share of royalties?

STATEMENT PURSUANT TO RULE 29.1

Respondent Sloan-Kettering Institute For Cancer Research states that it has no parent companies and also has no subsidiaries that are not wholly owned

TABLE OF CONTENTS

Page

COUNTERSTATEMENT OF THE QUESTION PRESENTED i

STATEMENT PURSUANT TO RULE 29.1 ii

TABLE OF AUTHORITIES iv

COUNTERSTATEMENT OF THE CASE 1

REASONS FOR DENYING THE WRIT 4

THERE ARE NO SPECIAL OR IMPORTANT REASONS FOR REVIEW 4

THE DISTRICT COURT FULLY CONSIDERED AND CORRECTLY DECIDED THE ISSUE, AND THE COURT OF APPEALS PROPERLY AFFIRMED 5

A. The Statutory Language 5

B. The Legislative History 7

CONCLUSION 10

TABLE OF AUTHORITIES

CASES **PAGE**

Arizona v. *Mauro*,
481 U.S. 520 (1987) 4

Beam v. *IPCO Corp.*,
838 F.2d 242 (7th Cir. 1988) 3

Blue Chip Stamps v. *Manor Drug Stores*,
421 U.S. 723 (1975) 5

Gilliard v. *Mississippi*,
464 U.S. 867 (1983) 4

I.N.S. v. *Cardoza-Fonseca*,
480 U.S. 421 (1987) 7

Marks v. *United States*,
430 U.S. 188 (1977) 4

Massachusetts Trustees of E. Gas and Fuel Assocs. v. *United States*,
377 U.S. 235 (1964) 4

McCray v. *New York*,
461 U.S. 961 (1983) 4

Shapiro v. *United States*,
335 U.S. 1 (1948) 9

Stein v. *United Artists Corp.*,
691 F.2d 885 (9th Cir. 1982) 3

United States v. *James*,
478 U.S. 597 (1986) 5

STATUTES AND RULES **PAGE**

7 U.S.C. § 329 6

10 U.S.C. § 1434 6

15 U.S.C. § 4224 (a)(5)(A) 6

16 U.S.C.
§ 1103 6
§ 839d(m) 6

20 U.S.C. § 959 6

22 U.S.C. § 2453(c) 6

35 U.S.C.
§ 202(a) 6
§ 202(c) 7
§ 202(c)(1) 6
§ 202(c)(3) 6
§ 202(c)(7)(B) . . . . . passim
§ 202(c)(7)(C) 8,9
§ 202(c)(7)(D) 6
§ 202(c)(8) 6
§ 203 7
§ 204 7

43 U.S.C. § 617d(d) (1988) 6

Pub. Law No. 98-115 § 806,
97 Stat. 786 (1983) 6

37 C.F.R. § 401.14(k) 9

46 Fed. Reg. 62548 (1981) 9

STATUTES AND RULES **PAGE**

Sup. Ct. R.
10.1(a) 4
10.1(c) 4
15 2

LEGISLATIVE MATERIAL

H.R. Rep. No. 1307, 96th Cong.,
2d Sess., pt. 1 (1980),
reprinted in 1980 U.S. Code Cong.
& Admin. News 6460 ("House Report") 8

S. Rep. No. 480, 96th Cong.,
1st Sess. (1979) ("Senate Report") 8,9

OTHER AUTHORITIES

Black's Law Dictionary (5th ed. 1979) 5,6

New Webster's Dictionary of the
English Language (3d ed. 1981) 5

No. 92-1345

IN THE
Supreme Court of the United States
October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE
and DR. ROLAND MERTELSMANN,

Petitioners,

v.

SLOAN-KETTERING INSTITUTE FOR
CANCER RESEARCH,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

COUNTERSTATEMENT OF THE CASE

Although petitioners acknowledge that their federal claims are "all derived from and dependent on" one phrase in a statute enacted over twelve years ago (P. 9),[1/] they admit that no court has even been called upon to construe that statute prior to this case (P. 11). On its face, therefore, the petition presents no questions of law that recur with any frequency, much less any on which the lower courts are in conflict. Accordingly, the decision of the United States District Court for the Southern District of New York, which was unanimously affirmed without opinion by the United States Court of Appeals for the Federal Circuit, presents no issues worthy of this Court's review.

[1/] Citations to "P. __" refer to pages of the Petition for Writ of Certiorari.

The basic facts material to this petition are simple and substantially undisputed. However, petitioners omit certain critical facts alleged in their own complaint, distort the holdings of the district court, and rely upon facts which were not properly part of the record below. Since these misstatements may "have a bearing on the question of what issues would properly be before the Court if certiorari were granted" (Sup. Ct. R. 15), we address them briefly here.

Petitioners frame both the "question presented" and their basic argument under 35 U.S.C. § 202(c)(7)(B), on the premise that the research funding agreement between the respondent Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering") and the federal government does not contain any provision for the sharing of royalties (P. i, 6). This supposed omission, petitioners argue, leaves respondent free to "pay its inventors any amount it unilaterally chooses, and avoid administrative or judicial review" (P. 5). This argument simply contradicts what is alleged in petitioners' own complaint, despite their express recognition that "the allegations contained in the complaint . . . must be assumed to be true" (P. 6). The complaint alleges that all funding agreements between Sloan-Kettering and the federal government *did* include, either expressly or by operation of law, the requirement that royalties be shared with inventors (Cmplt. ¶¶ 28, 41, 45 and 49).[2/] Since those funding agreements were between Sloan-Kettering and a federal agency, they obviously did not escape "administrative . . . review" (P. 5). Petitioners thus ignore the district court's unassailable conclusion that the "executive agency charged with administering" the Bayh-Dole Act "has expressly declined to establish any 'minimum sharing formula' on the ground that to do so would be 'inconsistent with the legislative intent'" (A. 19a).[3/]

In this unique case, the enormous commercial potential of G-CSF created a royalty stream that vastly exceeded the top range

---

[2/] The Complaint filed in the United States District Court for the Southern District of New York, dated September 30, 1991, is annexed hereto as Appendix A (hereafter, "Cmplt.").

[3/] Citations to "A. __" refer to pages of the Appendix to the Petition for Writ of Certiorari.

of the sliding scale in Sloan-Kettering's Patent Policy, so that the *more than $2.5 million* paid in 1990 to the five inventors as a group came to 5.05% of the gross 1990 royalties—still, by any standard, a handsome amount and a more than adequate incentive to salaried research scientists.[4] Nevertheless, petitioners seek to portray these payments as unreasonable by referring to alleged facts *not* contained in their complaint, but rather annexed in their own attorney's affidavit, improperly submitted on the motion to dismiss (P. 8). While petitioners continue to trumpet their counsel's affidavit as a "compelling schedule" (P. 8), the fact is that its hearsay comparison of Sloan-Kettering's Patent Policy to alleged royalty distribution policies at other institutions played no part whatever in the lower courts' rulings, is irrelevant to the issue of statutory construction on which those courts ruled, and should properly be ignored by this Court as well. *Beam* v. *IPCO Corp.*, 838 F.2d 242, 244 (7th Cir. 1988); *Stein* v. *United Artists Corp.*, 691 F.2d 885, 889 (9th Cir. 1982).[5]

---

[4] Sloan-Kettering shared the G-CSF royalties with the five inventors by distributing over $2.5 million, calculated according to the sliding scale formula in Sloan-Kettering's "Policy on Inventions, Patents, and Technology Transfer," which gave the inventors *25%* of the first $50,000 in gross royalties received by Sloan-Kettering, *15%* of the next $100,000 and *10%* of the next $150,000, plus *5%* of the remainder up to $50 million (A. 5a; Cmplt. ¶ 31). Sloan-Kettering also informed petitioners that they would receive further payments from any future royalties based on the same formula (A. 6a).

[5] Some of the petitioners' other statement of facts are likewise based upon material beyond the allegations of the complaint. This includes assertions concerning petitioners' employment agreements (P. 6); Sloan-Kettering's alleged lack of financial contribution to the research (*id.*); reference to an *amicus curiae* brief which the Court of Appeals specifically denied leave to file (P. 12 n.9); and an article published in the *Washington Post* after the Court of Appeals affirmed the district court decision (P. 7).

REASONS FOR DENYING THE WRIT

I. THERE ARE NO SPECIAL OR IMPORTANT REASONS FOR REVIEW

In considering this petition, the Court need not even reach the merits of the issue presented, because it is not one which is appropriate for review under any of this Court's established criteria.

Petitioners admit that "[t]his is the first case to arise in *any* court requiring judicial interpretation of the Bayh-Dole Act" (P. 11; *emphasis added*). The fact that only one such case has been filed in the twelve years since the Bayh-Dole Act became law demonstrates by itself that the question petitioners present is not ripe for this Court's attention. There has been no development in the lower courts that would even begin to suggest that the issue is likely to arise again—much less that it will be frequently litigated. *See e.g.*, *Massachusetts Trustees of E. Gas and Fuel Assocs.* v. *United States*, 377 U.S. 235, 237 (1964).

Even if the issue were perceived to be one of broad importance, as petitioners insist, this Court's usual practice is to postpone consideration until more than one case has enabled lower courts to consider the question and suggest solutions. *See*, *e.g.*, *Gilliard* v. *Mississippi*, 464 U.S. 867, 869 (1983) (Marshall, J., dissenting from denial of certiorari). Moreover, since this is a case of first impression, there is concededly "no conflict of decision within the federal system." *McCray* v. *New York*, 461 U.S. 961, 963 (1983); *see also* Sup. Ct. R. 10.1(a). Finally, petitioners do not even suggest that the decisions below represent a significant departure "from the accepted or usual course of judicial proceedings" (Sup. Ct. R. 10.1(a); *see also Marks* v. *United States*, 430 U.S. 188, 189 (1977)), or that they "conflict with applicable decisions of this Court" (Sup. Ct. R. 10.1(c); *see also Arizona* v. *Mauro*, 481 U.S. 520, 525 (1987)).

In sum, other than their self-serving assertion that the question is important, petitioners cannot fit this case within any of the established criteria for granting a writ of certiorari. Moreover, as shown below, the decisions below were sound.

II. THE DISTRICT COURT FULLY CONSIDERED AND CORRECTLY DECIDED THE ISSUE, AND THE COURT OF APPEALS PROPERLY AFFIRMED

The district court made two clear and simple holdings—(1) that "no private cause of action exists under § 202(c)(7)(B) of the Bayh-Dole Act" (A. 13a) and (2) that "the language of the statute, its legislative history, and subsequent agency regulations fail[] to suggest that Congress intended that institutions follow a federally imposed sharing ratio or minimum share" (A. 19a). The petition apparently does not seek review of the first holding, and its challenge to the second is based on an incomplete and misleading presentation of both the statutory language and the legislative history.

A. The Statutory Language

"The starting point in statutory interpretation is 'the language [of the statute] itself,'" based on the ordinary understanding of the words chosen by Congress. *United States* v. *James*, 478 U.S. 597, 604 (1986), *quoting Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 756 (1975) (Powell, J., concurring). The statute upon which plaintiffs premise all of their claims requires *only* that "[e]ach funding agreement with a . . . non-profit organization shall contain appropriate provisions" requiring, among *numerous* other things, that "the contractor share royalties with the inventor." 35 U.S.C. § 202(c)(7)(B) (1988). The words Congress chose clearly establish no formulas or guidelines concerning the amount of royalties to be paid to inventors. They merely impose an obligation *on federal granting agencies* to ensure that their funding agreements with nonprofit institutions include *some* provision for sharing royalties with individual inventors. The complaint alleges that Sloan-Kettering's funding agreements *do* contain such provisions (*see* p. 2 *supra*) and Sloan-Kettering has unquestionably complied with its contractual obligation by paying more than $505,000 to each inventor, with more to come.

Nothing on the face of the statute indicates that more is required. As the district court noted, "in common usage, the unmodified verb share means simply 'to have a share: take part.'" (A. 18a, *citing* New Webster's Dictionary of the English Language 2087 (3d ed. 1981)). Indeed, Black's Law Dictionary (5th ed.

1979) specifically *contrasts* the unmodified word "share," which it defines as "[t]o partake; enjoy with others; have a portion of," with the term "share and share alike," which is defined as referring to "*equal* shares or proportions." *Id.* That Congress used the unmodified verb advisedly in this instance is clear from the fact that, when Congress so intends, it has regularly specified that shares be equal.[9]

Unable to find anything helpful in the language Congress actually used in section 202(c)(7)(B), petitioners try to engraft an implied provision that the inventor's share "must be reasonable" (P. 13 n.8), and a corollary that what is "reasonable" in any given circumstance must be determined by courts and juries (P. 9). But this statute does not contain any express requirement that the royalty-sharing be "reasonable" or that it meet any equivalent standard. In sharp contrast, where Congress has intended in other contexts to require someone to pay a "reasonable share," it has expressly so provided in the statutory language.[7] More to the point, Congress used the word "reasonable" *seven times* in section 202—*the very statutory provision before this Court!*[8] But it

---

[9] *See, e.g.*, 7 U.S.C. § 329 (1988) (sums appropriated to be distributed to the states and territories "in equal shares"); 10 U.S.C. § 1434 (1988) (annuities payable to surviving children "in equal shares"); 16 U.S.C. § 1103 (1988) ("equal shares" of revenues to United States and Canada); 20 U.S.C. § 959 (1988) (donations to be distributed "in equal shares" to eligible federal agencies).

[7] *See, e.g.*, Pub. Law No. 98-115 § 806, 97 Stat. 786 (1983) (requiring that a "reasonable share" of architect/engineer contracts be set aside for small businesses, and expressly providing how it is to be determined); 22 U.S.C. § 2453(c) (1988) ("reasonable share" of cost of cultural exchange programs to be paid by the government); 43 U.S.C. § 617d(d) (1988) (requiring payment by agency using energy transmission line of "a reasonable share of the cost of construction, operation and maintenance"); 15 U.S.C. § 4224(a)(5)(A)(1988) (contractors must pay "a reasonable and proportionate share" of costs for all civilian government property they use); 16 U.S.C. § 839d(m) (1988) (federal power system must offer "a reasonable share" of resources to each regional utility).

[8] *See* 35 U.S.C. § 202(a) ("a reasonable time"); § 202(c)(1) ("a reasonable time"); § 202(c)(3) ("within reasonable times"); § 202(c)(7)(D) ("a reasonable inquiry"); and § 202(c)(8) (referring to "terms reasonable under the (continued...)

noticeably did not use that term, or any synonym, to modify the word "share" in section 202(c)(7)(B). The inescapable conclusion is that it did not intend to impose such a standard.

Petitioners' last-ditch effort is to seize upon the word "appropriate" in the introductory sentence of section 202(c), and argue that this adjective was (1) meant to modify "share" (P. 5) and (2) used to mean the "equivalent" of "reasonable" (P. 13 n.8). Neither argument has the slightest contextual support in the statute. First, the word "appropriate" clearly modifies "provisions"—i.e., the list of terms which are to be included in the funding agreement—not the word "share" as petitioners assert. Indeed, seven paragraphs and approximately 800 words separate the word "appropriate" from the word "share" in section 202(c). Second, construing "appropriate" as the "equivalent" of "reasonable" would lead to an absurd result. Could Congress really have intended that *each* of the twelve mandated provisions in funding agreements be "reasonable"—particularly when it used that precise word seven separate times in some, but not all, of the subsections enunciating those provisions? Congress could not have intended to write such a confusing statute—and it did not.

B. The Legislative History

With statutory language as clear and unambiguous as this, resort to the legislative history should hardly be necessary. But it bears noting that petitioners' presentation is incomplete and misleading.

Because the plain language of the statute does not specify any formula for determining the inventor's share of royalties, the district court properly looked to the legislative history only to determine whether it contains any clear expression of congressional intent sufficient to overcome the strong presumption that "Congress expresses its intent through the language it chooses." *I.N.S.* v. *Cardoza-Fonseca*, 480 U.S. 421, 432 n.12 (1987). In this instance, far from conflicting with the plain language, the legislative history adds compelling support to the view that Congress *never intended*

[9/](...continued)
circumstances" and "reasonable . . . efforts" contained in §§ 203 and 204 respectively).

to impose any specific sharing formula—much less to require that nonprofit institutions share royalties "reasonably" with inventors on terms to be determined by juries. Indeed, it demonstrates that Congress expressly *declined* to establish sharing ratios.

Seizing myopically on the fact that some royalty-sharing with inventors was contemplated, petitioners lose sight of the central purpose of the Bayh-Dole Act as a whole. Congress enacted the Bayh-Dole Act in 1980 because it was concerned about mounting evidence that the United States was falling behind in the development and commercial exploitation of patentable inventions, even as the federal government assumed a greater role in supporting basic scientific research. S. Rep. No. 480, 96th Cong., 1st Sess. (1979) at 1 ("Senate Report"); H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt. 1 (1980) at 2, *reprinted in* 1980 U.S. Code Cong. & Admin. News 6460 ("House Report"). With a view to easing the government's financial burden, Congress acted "to promote the utilization and commercialization of inventions made with Government support . . . and *stimulate a greater return* on the billions of dollars spent each year by the government *on its research and development programs*." Senate Report at 3 (emphasis added); *see also* House Report at 2.

To that end, the statute sought to ensure that nonprofit institutions would contribute the royalties resulting from government-sponsored research to support further scientific research. House Report at 5; Senate Report at 30; *see also* 35 U.S.C. § 202(c)(7)(C) (1988). The legislative history thus emphasizes that neither nonprofit institutions nor individual inventors should receive "windfall profits" from federally-funded inventions. Senate Report at 18, quoting the Draft Report on Patent Policy, Advisory Subcommittee on Patent and Information Policy of the Advisory Committee on Industrial Innovation (1978); *see also id.* at 30. However, Congress received testimony suggesting that allotting *some* royalty share for inventors would serve as an incentive for scientists and academics to *identify patentable discoveries* and *remain involved in the time-consuming paperwork* necessary to obtain a patent. Surely, the more than half a million dollars each petitioner here has received (with more to come) is, by any definition, "significant financial incentive[]" (P. 4) for researchers to cooperate in patenting and developing their discoveries.

The only snippet of legislative history cited by petitioners in support of their argument (P. 5) is one sentence contained in the 39-page Senate Report. But the paragraph in which that snippet is contained reads in full:

> Section 202(c)(7)(C), gives special recognition to the equity of inventors, and requires that nonprofit organizations share royalties with them. *It is not intended that Federal agencies establish sharing ratios*. Senate Report at 33 (emphasis added).

The very next section of the Senate Report reiterates that the statute "requires nonprofit organizations to use the net proceeds of their licensing efforts to further scientific research and education." Senate Report at 33.

The Senate Report thus expressly *repudiates* the notion that the statute imposes any particular formula for sharing, or even authorizes administrative agencies to do so. Had the administrative agency charged with enforcement of the Bayh-Dole Act interpreted the statute as mandating that institutions share a minimum (or even "reasonable") amount of royalties with inventors, it could easily have so provided. Instead, the Department of Health and Human Services ("HHS") expressly ruled that Congress did *not* authorize the executive branch to establish any specific royalty-sharing formulas. 46 Fed. Reg. 62548 (1981). HHS simply reverted to the statutory language, calling for contractual terms providing that the "contractor will share royalties collected on a subject invention with the inventor." 37 C.F.R. § 401.14(k) (1991).

Petitioners are therefore wrong when they tell this Court that support of on-going scientific research was only an "incidental" effect of the Bayh-Dole Act (P. 11). The district court's conclusion that "Congress' concern was with the reinvesting of funds to further research, not with furthering the private interests of individual inventors" (A. 19a) is amply supported by the legislative history. As the district court observed (A. 13a), allowing juries to award inventors up to 50% of royalties, after costly litigation and trial, would clearly frustrate, rather than further, that congressional intent. *Cf. Shapiro* v. *United States*, 335 U.S. 1, 31 (1948) (courts should adopt statutory construction "which

effectuates rather than frustrates the major purpose" of the legislation.)

In sum, nothing in *this* statute, its legislative history or its subsequent administrative interpretation supports petitioner's claim that it is within the province of a court or jury to determine in each case the sharing of royalties under section 202. Because the lower courts correctly decided the issue presented, this Court should deny the petition.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari to the United States Court of Appeals for the Federal Circuit should be denied.

Dated: New York, New York
March 5, 1993

Steven B. Rosenfeld
1285 Avenue of the Americas
New York, New York 10019-6064
(212) 373-3000

Counsel of Record for Respondent

Of Counsel:

Catherine J. Ross
Kathleen M. Walker

PAUL, WEISS, RIFKIND, WHARTON & GARRISON

APPENDIX—COMPLAINT OF PLAINTIFFS DR. ERICH PLATZER, DR. KARL WELTE AND DR. ROLAND MERTELSMANN DATED SEPTEMBER 30, 1991

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Plaintiffs,

-against-

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Defendant.

91 Civ. 6578 (JSM)

COMPLAINT

----------x

Plaintiffs, Dr. Erich Platzer, Dr. Karl Welte, and Dr. Roland Mertelsmann, by their attorneys, Gold, Farrell & Marks, for their complaint against defendant Sloan-Kettering Institute for Cancer Research ("SKI"), allege:

Jurisdiction and Venue

1. Plaintiff Dr. Erich Platzer is a citizen and resident of the Federal Republic of Germany.

2. Plaintiff Dr. Karl Welte is a citizen and resident of the Federal Republic of Germany.

3. Plaintiff Dr. Roland Mertelsmann is a citizen of the United States and is both a resident of the City, State and Southern District of New York, and of the Federal Republic of Germany.

4. Upon information and belief, defendant SKI is a not-for-profit corporation, organized under the laws of the State of New York with its principal place of business located within the City, State and Southern District of New York.

5. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because the claims arise under the patent laws and policies of the United States and require construction and interpretation of such laws. This Court has jurisdiction of other claims under principles of pendent jurisdiction.

6. Venue in this Court is proper on the ground that defendant is located within the City, State and Southern District of New York, and the claims have arisen therein.

The Parties And Their Dispute

7. This action involves the rights of three research physicians to share the royalties flowing as a result of their federally funded inventive research, conducted at SKI. The subject matter of their research was hemopoietins, the hormones which induce production of various kinds of blood cells in human beings. Several years ago the medical research community recognized that the production of these hormones "may effect a revolution in medicine as profound as the introduction of antibiotics half a century ago." (Golde & Gasson, *Hormones That Stimulate the Growth of Blood Cells*, *Scientific American*, July 1988, p. 62).

8. Plaintiffs' research at SKI was funded with grants provided by the United States Government. The salaries of Drs. Platzer and Welte while at SKI were, in part, paid with grants provided by the Federal Republic of Germany. Incurring virtually no expenses, SKI has already realized $50 million in royalties from the fruits of plaintiffs' research, and over the next several years SKI is likely to realize hundreds of millions of dollars more in further royalties.

9. Despite federal patent law requirements that these sums be shared with plaintiffs, SKI has paid each plaintiff only approximately 1%

of the sums it has received, and has refused to pay larger portions to plaintiffs from future royalties to be received.

10. Plaintiffs' specific research at SKI concerned granulocyte colony stimulating factor ("G-CSF"). G-CSF stimulates the proliferation and differentiation, and thereby the production, of neutrophilic granulocytes from bone marrow progenitor cells. Neutrophils are white blood cells essential to the body's immune system and defense mechanisms against infection. Plaintiffs' revolutionary invention was the underlying discovery and process necessary to permit the manufacture, using recombinant technology, of G-CSF, which is now prescribed and marketed in the United States (under the brand name "Neupogen") and throughout much of the world. G-CSF is used in conjunction with chemotherapy administered to cancer patients. Such treatments often cause the destruction of neutrophil production, leading to neutropenia, which in turn exposes patients to increased risk of life-threatening infections. Because G-CSF stimulates the production of neutrophils, it thereby materially reduces the deleterious side-effects of such treatment, and enables patients to tolerate therapeutic dosages which otherwise might have to be reduced due to toxicity. G-CSF will likely have many other significant medical applications for the prevention and treatment of neutropenia, including bone marrow transplants, burn treatment, concomitant AIDS therapy and treatment of other forms of chronic neutropenia.

11. The financial impact of plaintiffs' invention is equally impressive. It has been estimated that sales of G-CSF drugs will be at least $600 million annually over the next five years. SKI has already received an advance of $50 million for its rights to royalties for domestic sales of G-CSF. SKI has virtually no expenses to pay from these funds since the G-CSF research was financed with government funds. Nevertheless, SKI has paid to each of the plaintiffs only approximately 1% of these proceeds.

12. Plaintiffs bring this action for judgment declaring that pursuant to statute, statutorily required contractual provisions which are a part of the government funding agreements, the agreements between the parties and common law principles, plaintiffs are three of the five

inventors of G-CSF, that the inventors are together entitled to receive and share 50% of G-CSF royalties as and when received by defendant, or a fair and reasonable portion of all royalties, and for judgment against defendant allocating royalties previously received, calculated in such manner.

Governing Laws

13. The purpose of the United States patent laws is "To promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries." (U.S. Constitution, Article I, Section 8, Clause 8.)

14. In furtherance of this purpose, the federal government has, for many years, funded research at non-profit institutions, such as SKI. In 1980, in an effort to stimulate inventions arising from federally supported research and development, Congress fundamentally altered United States patent policy to encourage nonprofit organizations to obtain patents to inventions and to commercially market such inventions for profit. (35 U.S.C. § 200 *et seq.*, Pub. L. 96-517, 94 Stat. 3019, effective July 1, 1981).

15. The 1980 legislation grants non-profit organizations the exclusive title to inventions developed through federally funded research and development, and allows them to freely license such inventions. In addition, the statute provides, in pertinent part:

> Each funding agreement with a . . . nonprofit organization shall contain appropriate provisions to effectuate the following: . . . (B) a requirement that the contractor share royalties with the inventor. . . .

35 U.S.C. § 202(c)(7)(B) ("§ 202(c)(7)(B)").

16. The purpose of § 202(c)(7)(B) is to ensure that inventors are fairly compensated for their labors, and that they are thereby given

the incentive to fulfill the Constitutional and statutory intent of encouraging new inventions and technology for the public welfare.

Facts

17. Dr. Erich Platzer was educated in Bavaria, Germany and acquired a diverse background in physics and mathematics before undertaking his medical studies. While pursuing his doctoral studies, Dr. Platzer became involved in clinical immunology at the Department of Immunology at Erlangen, Germany, where he earned his medical degree. Upon completion of his medical studies, Dr. Platzer continued his research in the immune systems of cancer patients.

18. Dr. Karl Welte earned his medical degree in West Berlin, Germany. Following a residency in the Department of Pediatric Hematology and Oncology at the Children's Hospital, West Berlin, Dr. Welte became a research and clinical fellow in the areas of molecular biology, pediatric hematology and oncology. Dr. Welte's research included the purification and the biochemical and immunological characterization of viral enzymes from human cancer tissues and tumors.

19. Dr. Roland Mertelsmann earned his medical degree from the University of Hamburg, Germany where he remained as a resident in Internal Medicine, Medical Oncology and Hematology. He also served as Assistant Professor of Medicine and earned his Ph.D. at the University of Hamburg. From 1976 through 1984 he conducted research at SKI, and was an Attending Physician at Memorial Sloan-Kettering Cancer Center ("MSKCC") and a Professor of Medicine at Cornell University Medical College. He conducted and supervised research in Oncology and Hematology. He is presently a Professor of Medicine at Freiburg University Medical Center, Freiburg, Germany.

20. Beginning in 1981, Drs. Platzer and Welte conducted research at SKI. Both were supported by research grants funded by the Federal Republic of Germany. Dr. Platzer's research was initially focused on inhibitory molecules of hematopoiesis, in collaboration with Dr. Hal Broxmeyer. Dr. Welte, working in collaboration with Dr. Mertelsmann, succeeded in purifying to homogeneity the human

T-cell growth factor now known as Interleukin-2. Dr. Platzer left SKI in 1984 and returned to Germany. He presently is a Privatdozent of Internal Medicine, Attending Physician and Senior Researcher at the University of Erlangen. Dr. Welte remained at SKI until 1987 when he returned to Germany, and between 1985 and 1987, he was head of the Laboratory of Cytokine Biology. He is presently a Professor of Pediatrics in Hannover, Germany.

21. In or about January 1982, Dr. Platzer began focusing his research on certain colony stimulating factors, naturally produced in humans, which induce the production of various types of blood cells in bone marrow. His goal was to purify such substances for amino acid sequencing, in order to allow isolation of encoding C-DNA clones for commercial production. Dr. Platzer hypothesized that a collaboration with Dr. Welte held promise of furthering such a project, and Drs. Platzer and Welte thereupon decided to pursue such research together.

22. In furtherance of such purpose, from 1982 to 1984, Drs. Platzer and Welte conducted their research together at SKI, often working in collaboration with Drs. Mertelsmann, Gabrilove and Moore. By fall 1983, they had successfully purified G-CSF to the extent that it could be amino acid sequenced.

23. Subsequent repetitive application of this purification procedure by plaintiffs ultimately enabled the cloning of encoding C-DNA clones, which resulted in commercial production of G-CSF.

24. Dr. Mertelsmann was head of the Laboratory of Molecular Hematology at SKI at which Dr. Welte performed research. Dr. Mertelsmann collaborated with Dr. Welte and contributed to the purification of G-CSF.

25. Dr. Janice Gabrilove, then a clinical fellow at MSKCC, performed research in the laboratory in which Dr. Platzer worked. She contributed to the purification of G-CSF. Dr. Gabrilove continues to be employed by MSKCC and/or SKI.

26. Dr. Malcolm A. S. Moore was head of the Department of Developmental Hematopoiesis of SKI at which Drs. Platzer, Welte and Gabrilove performed research. Dr. Moore contributed to the purification of G-CSF. Dr. Moore continues to be employed by MSKCC and/or SKI.

27. Drs. Platzer, Welte, Mertelsmann, Gabrilove, and Moore are inventors of G-CSF for all relevant purposes herein.

28. The aforesaid research conducted at SKI which led to the purification of G-CSF was funded and supported by the United States pursuant to funding agreements. At all times relevant herein, the terms and conditions of such government funding agreements included the statutory "requirement that [SKI] share royalties with the inventor", required by § 202(c)(7)(B).

29. At all times relevant herein, it was a part and condition of the agreements of employment between Drs. Platzer, Welte, and Mertelsmann and SKI, and a covenant thereof, that the parties would abide by all government statutes and regulations applicable to government financed research, including the requirements that proprietary rights to inventions would be owned by SKI and assigned to it by Drs. Platzer, Welte, and Mertelsmann, and that SKI would share royalties with Drs. Platzer, Welte, and Mertelsmann in accordance with § 202(c)(7)(B).

30. Upon information and belief, on or about February 12, 1986, SKI granted an exclusive worldwide license for G-CSF to Amgen, Inc., a Delaware corporation in the pharmaceutical business with principal offices located in Thousand Oaks, California. Under the terms of such licensing agreement, SKI would receive percentages of Amgen's net sales. In addition, SKI and Amgen, Inc. agreed that the licensing agreement would be subject to applicable federal government patent statutes and regulations.

31. At a time unknown to plaintiffs, and without giving plaintiffs any notice thereof, upon information and belief, SKI unilaterally adopted a policy of distributing to inventors a portion of the

annual gross proceeds derived from inventions and discoveries ("SKI Policy"). The SKI Policy provides for distribution to inventors of the following proportion of the annual gross proceeds of their inventions, as follows:

$0–$50,000	25%
$50,000–$150,000	15%
$150,000–$300,000	10%
over $300,000	5%

32. On or about November 26, 1990, SKI wrote to plaintiffs to advise them that the licensing agreement with Amgen, Inc. had been amended and that SKI was then receiving a $50 million fee in exchange for its rights to royalties for U.S. sales of plaintiffs' invention, and would receive an additional $10 million after three years of United States sales without competition, and an additional $15 million after five years of U.S. sales without competition. SKI informed plaintiffs that it would receive additional royalties from domestic sales, and royalties from foreign sales as originally planned.

33. Purporting to apply the SKI Policy, SKI advised plaintiffs that they would each receive $505,490, representing approximately 1% of the amount received by SKI. The said sum was received by each plaintiff shortly thereafter.

34. The meaning and intent of § 202(c)(7)(B) is that the "contractor" (SKI) is to share royalties *equally* with the "inventor" (plaintiffs), *i.e.*, the inventors would together receive a total of 50% of all royalties received by SKI.

35. Alternatively, the meaning and intent of § 202(c)(7)(B) is that the "contractor" is to share royalties on a fair and equitable basis with the inventors. Sharing royalties on a fair and equitable basis would also require that SKI pay 50% of all royalties received with the inventors.

36. Many non-profit research institutions have adopted policies of allocating portions of royalties to inventors, purporting to comply with § 202(c)(7)(B). Upon information and belief, at least one preeminent American research institution has adopted plaintiffs' interpretation of § 202(c)(7)(B), and such institution pays 50% of royalties to inventors. Most other institutions have adopted policies pursuant to which they pay between 15% and 40% of royalties to inventors. Plaintiffs are unaware of any other institution which has a policy which is anywhere as parsimonious as the restrictive and overreaching policy which SKI has enforced against plaintiffs.

37. The aforesaid payments made to plaintiffs do not comply with the legal requirements of § 202(c)(7)(B), pursuant to which SKI is required to have been paid the inventors 50%, or a fair or reasonable portion, of the royalties received, which would amount to $25 million.

38. The aforesaid payments made to plaintiffs do not comply with the SKI Policy, which SKI claims is applicable. That policy requires that inventors' shares are to be calculated upon "annual gross proceeds derived from an invention or discovery", not merely upon receipts by SKI. Upon information and belief, such annual gross proceeds will be in excess of $600 million annually worldwide over five years. Applying the SKI Policy, the inventors would together be entitled to receive a total of approximately $150 million over such five year period.

39. An actual controversy exists between plaintiffs and defendant within the meaning of 28 U.S.C. § 2201(a).

FIRST CLAIM FOR RELIEF
(Statutory Right of Action)

40. Plaintiffs repeat and reallege paragraphs 1-37 and 39 hereof.

41. Pursuant to § 202(c)(7)(B), SKI as a recipient of federal funding, is obligated to the inventors to share royalties with them, and is liable to them for breaching such statutory obligation.

42. SKI has breached its statutory obligation requiring it to share royalties with inventors by failing to pay plaintiffs and the other inventors a total of 50%, or a fair and a reasonable portion, of the royalties SKI has received and expects to receive from the commercial exploitation of G-CSF.

43. Plaintiffs have been damaged in an amount to be proved at trial, but not less than $13.5 million on account of past royalties. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF
(Third Party Beneficiary)

44. Plaintiffs repeat and reallege paragraphs 1-37 and 39 hereof.

45. Plaintiffs are third party beneficiaries of the statutorily mandated contractual provision contained in § 202(c)(7)(B) requiring SKI, as a recipient of federal funding, to share royalties with the inventors.

46. SKI has breached this provision requiring it to share royalties with inventors by failing to pay plaintiffs and the other inventors a total of 50%, or a fair and a reasonable portion, of the royalties SKI has received and expects to receive from the commercial exploitation of G-CSF.

47. Plaintiffs have been damaged in an amount to be proved at trial, but not less than $13.5 million on account of past royalties. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF
(Breach of Contract)

48. Plaintiffs repeat and reallege paragraphs 1-37 and 39 hereof.

49. The statutorily mandated contractual provision contained in § 202(c)(7)(B) requiring SKI, as a recipient of federal funding, to share royalties with the inventors was a part and condition of the agreements of employment between plaintiffs and SKI, and a covenant thereof.

50. SKI has breached this provision requiring it to share royalties with inventors by failing to pay plaintiffs and the other inventor a total of 50%, or a fair and a reasonable portion, of the royalties SKI has received and expects to receive from the commercial exploitation of G-CSF.

51. Plaintiffs have been damaged in an amount to be proved at trial, but not less than $13.5 million on account of past royalties. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

FOURTH CLAIM FOR RELIEF
(Breach of Contract—Alternative Pleading)

52. If the Court determines that the SKI Policy is binding upon the parties hereto, as a part and condition of the agreements of employment between plaintiffs and SKI, then plaintiffs are entitled to the relief set forth in this claim.

53. Plaintiffs repeat and reallege paragraphs 1-33 and 38-39 hereof.

54. Plaintiffs are entitled to receive sums calculated in accordance with the SKI Policy, but based upon annual gross proceeds

received by any person, based upon past and future sales, not merely based upon royalties received by SKI from Amgen, Inc.

55. SKI has breached this contractual obligation to plaintiffs by calculating the percentages payable to inventors under the SKI Policy only on the basis of royalties received by SKI from Amgen, Inc., rather than based upon annual gross proceeds received by any person as a result of sales of G-CSF, as is required under the SKI Policy.

56. Plaintiffs have been damaged in an amount to be proved at trial which plaintiffs presently believe to be approximately $18 million. In addition, they are entitled to a declaration of their rights with respect to future royalties, and an award of reasonable attorneys' fees.

FIFTH CLAIM FOR RELIEF
(Unjust Enrichment)

57. Plaintiffs repeat and reallege paragraphs 1-39, 41-43, 45-47, 49-51 and 54-56 hereof.

58. SKI has received and will continue to receive enormous financial benefits from sales of G-CSF throughout the world, solely as a result of plaintiffs' invention.

59. Plaintiffs are entitled to an award of damages in an amount to be proved at trial, but not less than their fair and reasonable inventors' share of all past and future royalties.

WHEREFORE, plaintiffs demand judgment, as follows:

A. On the first, second and third claims for relief, declaring the rights of the parties, and for judgment against defendant in an amount to be proved at trial based upon past receipts of royalties on account of G-CSF, in the amount of at least $13.5 million, together with attorneys' fees.

B. Alternatively, on the fourth claim for relief, declaring the rights of the parties and for judgment against defendant in an amount to be proved at trial based upon annual gross proceeds received by any person from sales of G-CSF, in the amount of at least $18 million, together with attorneys fees.

C. On the fifth claim for relief, declaring the rights of the parties and for judgment against defendant in an amount to be proved at trial.

D. On all claims for relief, for attorneys fees, interest, costs and disbursements and such other and further relief as the court deems just and proper.

Dated: New York, New York
September 30, 1991

GOLD, FARRELL & MARKS

By: /s/
Martin R. Gold, 6528
A Member of the Firm

41 Madison Avenue
New York, New York 10010
(212) 481-1700

Attorneys for Plaintiffs
Dr. Erich Platzer
Dr. Karl Welte
Dr. Roland Mertelsmann